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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,315	01/18/2002	Katharine M. Martin	J&J-2086	1178

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,315

Applicant(s)

MARTIN ET AL.

Examiner

Shaojia A Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19, 21, 22, 24-26 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19, 21-22, 24-26 and 28-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2003 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed October 30, 2003, and amendment and response to the Final Office Action (July 28, 2003), filed October 30, 2003 wherein claims 1-16, 18, and 20 (drawn to an invention nonelected) are cancelled, and claims 17, 19, 21-22, 24-26 and 28 have been amended, and claims 29-40 are newly added.

Currently, claims 17, 19, 21-22, 24-26 and 28-40 are pending in this application.

Claims 17, 19, 21-22, 24-26 and 28 as amended now and new claims 29-40 will be examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, 21-22, 24-26 and 28 as amended now and new claims 29-40 are rejected under 35 U.S.C. 112, first paragraph, for **scope** of enablement because the specification, while being enabling for treating, increasing or tightening the firmness of skin, i.e., preventing the loss of firmness or elasticity of skin, including preventing, retarding, arresting, or reversing the wrinkles in the skin (see page 3 lines 1-20 of the specification) disclosed in the specification employing a Hedychium extract herein, does not reasonably provide enablement for relaxing or decreasing the firmness of skin.

The skilled artisan would view that the recitation, "regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject", encompassing both increasing and decreasing the firmness, tone, or texture of skin of a subject or both increasing and decreasing wrinkles in skin of a subject, in both directions.

The instant claims are drawn to the methods for regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdAplS 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the methods for regulating, i.e., encompassing both increasing and decreasing the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject.

The state of the prior art: The skilled artisan would view that regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including increasing and decreasing the wrinkles in the skin, are highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that, regulating, encompassing both increasing and decreasing, the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject, is highly unpredictable since the skilled artisan would not understand how the same compound or agent could increase and decrease the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the herein to regulate the firmness, or tone of skin of a subject herein, or how to prevent, retard, arrest, or reverse the wrinkles in the skin. Applicant's specification provides the experimental results merely showing *in vitro* effects of a hedychium extract (see page 11-15 of the specification).

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to achieve methods of regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including preventing, retarding, arresting, or reversing the wrinkles in the skin, with no assurance of success.

Applicant's remarks and Exhibition A submitted October 30, 2003 have been fully considered but are not deemed persuasive as to the scope of enablement of the claimed invention. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant asserts that the claimed compositions have shown to achieve such regulation, for example, the product Renova®, the label has been approved by the FDA for the use in the mitigation (palliation) of fine wrinkles. However, the instant claims are not drawn to the treatment of the mitigation (palliation) of fine wrinkles, but methods of regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject. As indicated above, the recitation of "regulating" in the claims reads on decreasing the firmness tone, or texture of skin of a subject since regulation encompasses both increasing and decreasing the firmness tone, or texture of skin of a subject.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, 21-22, 24-26 and 28 as amended now and new claims 29-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd (JP 61291515), for the same reasons of record stated in the Office Action dated July 28, 2003.

Shiseido Co. Ltd discloses that a hedychium extract in an effective amount, within the instant claim, is useful in a cosmetic composition with a cosmetically-acceptable carrier for topical administration and a method of treating hot feeling after sunburn, rough skin, razor rash and inflammations. See in JP 61291515, the abstract, and examples at page 65-69. Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Shiseido Co. Ltd anticipates the claimed invention.

Applicant's remarks filed October 30, 2003 with respect to this rejection of claims 17, 19, and 21-28 made under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd. Of record have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicants assertion that "The '515 patent does not disclose the topical application of such a composition to such skin. Rather, the '515 Patent discloses the application to sunburned skins to rough skinz razor, rashed skin, and inflamed skin" is not found convincing because the treatment of hot feeling after sunburn, rough skin, razor rash and inflammation, is topical application to the skins. As discussed in the Office Action July 28, 2003, one of ordinary skill in the art would clearly recognize that sunburn, rough skin, razor rash and inflammation are liable to damage or affect skin firmness, tone, or cause wrinkles. Hence, the certainty for the inherent treatment herein as one criteria for determining inherency is clearly seen here, not mere probability or possibilities. The skin of the patient suffering after sunburn, rough skin, razor rash and inflammation would be certainly in need of such treatment because of affected or damaged skins as to the firmness, tone, or wrinkles of the skin in that patient.

Thus, as discussed in the previous Office Action, Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Shiseido Co. Ltd anticipates the claimed invention.

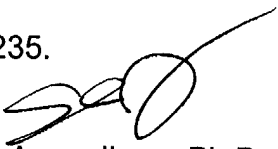
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In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 8, 2003